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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,772	10/17/2001	Gustav Levander	P02232US0-(1	1118

7590

09/24/2002

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EXAMINER

NOLAN, SANDRA M

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 09/24/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/889,772

Applicant(s)

LEVANDER ET AL.

Examiner

Sandra M. Nolan

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,10-12 and 14-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8,10-12 and 14-34 is/are rejected.
- 7) ☒ Claim(s) 1,3-5,10,14,23,24,29,30,32 and 33 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims

1. Pursuant to entry of the amendment of October 17, 2002 (Paper No. 5), claims 1-8, 10-12 and 14-34 are pending.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

3. Claims 1, 3-5, 10, 14, 23, 24, 29, 30, 32 and 33 are objected to because of the following informalities: "dicarboxylate", "naphthalenate" and "naphthalenic" are misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- W/D
5. Claims 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What does "sealing the product with a polymer material" mean? Is the polymer an adhesive/sealant for the nicotine product? Please clarify.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

K 7. Claims 1-3, 5-8, 10, ¹¹/₁12 and 14-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cubbage et al (US 5,804,215) in view of Hunter (US 6,037,033) and JP 04239607A (abstract).

Cubbage teaches the disposal of transdermal nicotine patches (col. 1, line 12) by wrapping them in disposal members made of laminated films of polyethylene terephthalate (col. 2, line 58). The disposal member is designed to encapsulate the patch and prevent access to it (abstract).

Cubbage does not teach polyethylene naphthalenate (PEN) or liquid crystal polymers (LCP's).

Hunter teaches LCP's containing naphthalenic acid moieties (col. 6, lines 1-34) and their use in multilayer systems (col. 6, line 8). The LCP's are taught to be gas barrier materials (col. 6, line 34).

N-bund > JP 04239607A teaches PEN and its gas barrier activity (Use/Advantage section).

The references are analogous because they all deal with the production/use of materials having gas barrier properties.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the PEN of the Japanese abstract and/or the LCP materials of Hunter as gas barrier layers in the nicotine patch disposal films of Cubbage in order to stabilize the films against the effects of the nicotine in the patch.

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The motivation to employ the PEN of the Japanese abstract and/or the LCP's of Hunter in the disposal system of Cubbage is found in the Use/Advantage section of the abstract and at col. 6, line 34 of Hunter, where gas barrier properties are ascribed to these materials.

It is deemed desirable to produce nicotine patch disposal films that are stable so that the nicotine in the patch inside the film cannot leach out and become a danger to children or pets that might find it.

The use of metal layers in barrier films is well known.

W/D 8. Claims 1-3, 5-8, 10-12 and 14-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derr (US 6,162,516) in view of Hunter and JP 04239607A.

Derr teaches that harm caused to the oral tissues in the mouth of a smokeless tobacco user can be reduced by the enclosing the tobacco, when in use, in a shield (Figure 2, features 1 and 2) of impermeable plastic (col. 9, lines 11 and 18).

It fails to teach the use of PEN or LCP's in the shield.

Hunter and JP 04239607A are discussed above.

The references are analogous because they all deal with impermeable plastics.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the PEN of the Japanese abstract and/or the LCP materials of Hunter as gas barrier layers in the shields of Derr in order to reduce the likelihood that the nicotine could pass through the shield and harm the smokeless tobacco user's oral tissues.

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The motivation to employ the PEN of the Japanese abstract and/or the LCP's of Hunter in the shield of Derr is found in the Use/Advantage section of the abstract and at col. 6, line 34 of Hunter, where gas barrier properties are ascribed to these materials.

It is deemed desirable to produce smokeless tobacco shields that prevent the transfer of nicotine through the shield and onto the oral tissues in order to minimize the likelihood of harm to those tissues.

The use of metal layers in barrier films is well known.

Use of the shields suggested by the combination of references to enclose lozenges or gum would be obvious, given nicotine's propensity to harm oral tissues.

Citation as of Interest

9. Harvey et al (US 6,241,349) shows the use of PEN and/or LCP's in containers.

Conclusion

Any inquiry concerning this communication should be directed to Sandra M. Nolan, whose telephone number is 703/308-9545. The Examiner can normally be reached on Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If you cannot reach the Examiner by telephone, her supervisor, Harold Pyon, can be reached at 703/308-4251. The general fax number for the art unit is 703/305-5436. The after final fax is 703/872-9310. The receptionist answers 703/308-0661.



S. M. Nolan
Patent Examiner
Technology Center 1700

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September 17, 2002